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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,334	07/23/2004	Junya Ishida	255578USOPCT	9828

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EXAMINER	
MURRAY, JEFFREY H	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	04/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/18/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/501,334	ISHIDA ET AL.
	Examiner	Art Unit
	Jeffrey H. Murray	1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. The compound or composition of formula (1), according to Claims 1,3-9 wherein $Y^1=Y^2$ is N=C and A is a seven-membered or larger nitrogen containing heterocyclic ring.
- II. The compound or composition of formula (1), according to Claims 1,3-9 wherein $Y^1=Y^2$ is N=C and A is a six-membered heterocyclic ring with at least 2 heteroatoms, at least one being nitrogen.
- III. The compound or composition of formula (1), according to Claims 1-9 wherein $Y^1=Y^2$ is N=C and A is a six-membered heterocyclic ring with one nitrogen.
- IV. The compound or composition of formula (1), according to Claims 1,3-9 wherein $Y^1=Y^2$ is N=C and A is a five-membered heterocyclic ring with at least one nitrogen.

- V. The compound or composition of formula (1), according to Claims 1-9 wherein $Y^1=Y^2$ is N=C and A is a sulfur containing heterocyclic ring with no nitrogen ring members.
- VI. The compound or composition of formula (1), according to Claims 1-9 wherein $Y^1=Y^2$ is N=C and A is an oxygen containing heterocyclic ring with no nitrogen or sulfur members.
- VII. The compound or composition of formula (1), according to Claims 1,3-4,6-9 wherein $Y^1=Y^2$ is C=N and A is a seven-membered or larger nitrogen containing heterocyclic ring.
- VIII. The compound or composition of formula (1), according to Claims 1,3-4,6-9 wherein $Y^1=Y^2$ is C=N and A is a six-membered heterocyclic ring with at least 2 heteroatoms, at least one being nitrogen.
- IX. The compound or composition of formula (1), according to Claims 1-4,6-9 wherein $Y^1=Y^2$ is C=N and A is a six-membered heterocyclic ring with one nitrogen.
- X. The compound or composition of formula (1), according to Claims 1,3-4,6-9 wherein $Y^1=Y^2$ is C=N and A is a five-membered heterocyclic ring with at least one nitrogen.
- XI. The compound or composition of formula (1), according to Claims 1-4,6-9 wherein $Y^1=Y^2$ is C=N and A is a sulfur containing heterocyclic ring with no nitrogen ring members.

- XII. The compound or composition of formula (1), according to Claims 1-4,6-9 wherein $Y^1=Y^2$ is C=N and A is an oxygen containing heterocyclic ring with no nitrogen or sulfur members.
- XIII. The compound or composition of formula (1), according to Claims 1,3-4,6-9 wherein $Y^1=Y^2$ is C=C and A is a seven-membered or larger nitrogen containing heterocyclic ring.
- XIV. The compound or composition of formula (1), according to Claims 1,3-4,6-9 wherein $Y^1=Y^2$ is C=C and A is a six-membered heterocyclic ring with at least 2 heteroatoms, at least one being nitrogen.
- XV. The compound or composition of formula (1), according to Claims 1-4,6-9 wherein $Y^1=Y^2$ is C=C and A is a six-membered heterocyclic ring with one nitrogen.
- XVI. The compound or composition of formula (1), according to Claims 1,3-4,6-9 wherein $Y^1=Y^2$ is C=C and A is a five-membered heterocyclic ring with at least one nitrogen.
- XVII. The compound or composition of formula (1), according to Claims 1-4,6-9 wherein $Y^1=Y^2$ is C=C and A is a sulfur containing heterocyclic ring with no nitrogen ring members.
- XVIII. The compound or composition of formula (1), according to Claims 1-4,6-9 wherein $Y^1=Y^2$ is C=C and A is an oxygen containing heterocyclic ring with no nitrogen or sulfur members.

- XIX. The compound or composition of formula (1), according to Claims 1-9
wherein $Y^1=Y^2$ is N=C and A is a phenyl ring.
- XX. The compound or composition of formula (1), according to Claims 1-4,6-9
wherein $Y^1=Y^2$ is C=N and A is a phenyl ring.
- XXI. The compound or composition of formula (1), according to Claims 1-4,6-9
wherein $Y^1=Y^2$ is C=C and A is a phenyl ring.
- XXII-XLIII. A method of inhibiting PARP activity comprising administering a
compound of the formula (1) as in Groups I-XIX according to Claim 10.
- XLIV-LXV. A method of manufacturing a compound of the formula (1), or its prodrug,
or its pharmaceutically accepted salt for a medicament for inhibiting PARP
activity as in Groups I-XIX according to Claim 11.

2. The inventions listed as Groups I - LXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the claims is a compound of formula (1). Prior art exists which causes the core structure in the current application to lack a special technical feature. When $Y^1=Y^2$ is N=C, and A is phenyl ring the core structure is a substituted quinazolin-4(3H)-one. This ring is seen in numerous patents and papers, for example: Pandey et. al.; *J. Med. Chem.* 2002, 45, 3774; which teaches the synthesis of both the 7-fluoroquinazolin-4(3H)-one and the 7-(2-methoxyethoxy)fluoroquinazolin-4(3H)-one. Therefore the feature linking the claims

does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art.

Accordingly, Groups I – LXV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

There are two separate species within the aforementioned claims as follows:

- 1) All the various combinations and subcombinations that exist by altering the Y¹=Y² and the A ring in the formula (1) ring system.
- 2) All the various diseases listed which cause cell damage and death.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:
Claims 2-6.

The following claim(s) are generic: Claim 1 and 9.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Inventions I-XXI and XXII-XLIII are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a 7-fluoroquinazolin-4(3H)-one and the 7-(2-methoxyethoxy)fluoroquinazolin-4(3H)-one are synthesized via a different procedure described in Pandey et. al.; *J. Med. Chem.* 2002, 45, 3774).

Inventions I-XXI are related to patentably distinct compounds or compositions having the formula (1). Inventions XLIV-LXV are related to patentably distinct methods of using compounds or compositions of Groups I-XXI. There is also no common core associated with the compounds and compositions of Groups I-XXI. A common core is important aspect in defining a single general inventive concept. Groups I-XXI follow the general formula (1), however, the formula is so broad between each of Groups I-XXI and also within each individual Group so as to not have a common core. Furthermore, formula (1) does not define a contribution over the prior art. The international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept under PCT Rule 13.

7. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

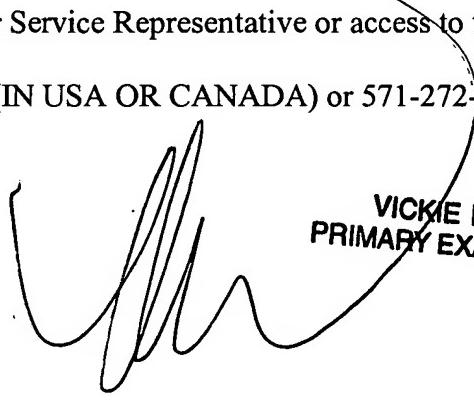
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is (571) 272-9023. The examiner can normally be reached on M-F 7:30-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang can be reached at 571-272-0562 or Janet Andres can be reached at 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey H. Murray



VICKIE KIM
PRIMARY EXAMINER